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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------------|------------------|
| 10/733,869 | 12/11/2003 | Jacho Kim | GUID.045PA (01-140) | 8095 |
| 51294 7590 03/09/2007 HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425 | | | EXAMINER EVANISKO, GEORGE ROBERT | |
| | | | ART UNIT 3762 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/09/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|---------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/733,869 | Applicant(s) YASUSHI ET AL | |
| | Examiner George R. Evanisko | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/27/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17, 19-35, 37, 39-55, 57, 59-62, 64, 66-69, 71-87 and 89-94 is/are rejected.
- 7) ☒ Claim(s) 18, 36, 38, 56, 58, 63, 65, 70 and 88 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims pertaining to fusion/pseudofusion is withdrawn in view of the newly discovered reference(s) to Levine et al. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4-8, 13, 14, 16, 17, 19, 20, 23, 39, 41, 48-51, 59, 73, 75, 79-82, 85, 86, 90, 92, and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al (6973350). Levine discloses in columns 18-25 the use of two non-overlapping windows, AERW and RDW, to classify the response to pacing as either capture, non-capture, or fusion/pseudofusion and further describes how the RDW window can be adjusted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 6-9, 13, 14, 16, 17, 19-25, 59, 60-62, 64, 66, 73, 75, 78-85, 90, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroepel (5431693) in view of Levine. Schroepel shows in figures 8 and 9 and discusses in columns 6-8 the use of two windows, one over 40-70 ms, and the second over 70-100 ms to classify the response based on a peak of a second derivative (the slope) of the cardiac signal. But Schroepel does not show the windows being used to classify fusion/pseudofusion. Levine discloses that it is known when a pacing system is determining capture/noncapture to use a plurality of windows with a window relating to fusion/pseudofusion since it helps determine fusion/pseudofusion in order to terminate pacing and help conserve power and/or extend the life of the power supply. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the pacing device and method as taught by Schroepel the use of a plurality of windows with a window relating to fusion/pseudofusion as taught by Levine since such modification would provide a pacing system and method with the use of a plurality of windows with a window relating to fusion/pseudofusion in order to terminate pacing and help conserve power and/or extend the life of the power supply

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Claims 1, 3, 4, 6-9, 12, 16, 17, 19, 20, 22, 23, 39, 41-44, 46-49, 50, 51, 73-76, 78-83, 85, 86, 87, 89, 90, 92, and 93 rejected under 35 U.S.C. 103(a) as being unpatentable Rueter et al (7027868) in view of Levine. Rueter discusses in columns 10-12 and figure 8 the use of three windows, 86, 88, and 90, to classify the AVC threshold test over 2 of 3 cycles and by delivering an atrial pulse and sensing in the ventricle and using either high to low or low to high pulses (column 8, line 53-65). But Rueter does not show the windows being used to classify fusion/pseudofusion. Levine discloses that it is known when a pacing system is determining capture/noncapture to use a plurality of windows with a window relating to fusion/pseudofusion since it helps determine fusion/pseudofusion in order to terminate pacing and help conserve power and/or extend the life of the power supply and Levine discloses that it is known to adjust one of the windows to account for conduction delays. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the pacing device and method as taught by Rueter the use of a plurality of windows with a window relating to fusion/pseudofusion as taught by Levine since such modification would provide a pacing system and method with the use of a plurality of windows with a window relating to fusion/pseudofusion in order to terminate pacing and help conserve power and/or extend the life of the power supply and to use an adjustment of one of the windows to account for conduction delays.

Claims 1, 3, 4, 6-9, 13, 14, 16, 17, 19, 20, 22, 23, 39, 41-43, 47-49, 50, 51, 59, 73, 75, 78-83, 85, 86, 87, 89, 90, and 92-94 rejected under 35 U.S.C. 103(a) as being unpatentable over Vonk (2002/0183798) in view of Levine. Vonk discloses in figures 9A and 9B and in

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paragraphs 75-88 the use of two non-overlapping windows, how the windows are dynamically adjusted, and how the threshold search is conducted using a FFRW peak (paragraph 65). But Vonk does not show the windows being used to classify fusion/pseudofusion. Levine discloses that it is known when a pacing system is determining capture/noncapture to use a plurality of windows with a window relating to fusion/pseudofusion since it helps determine fusion/pseudofusion in order to terminate pacing and help conserve power and/or extend the life of the power supply and Levine discloses that it is known to adjust one of the windows to account for conduction delays. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the pacing device and method as taught by Vonk the use of a plurality of windows with a window relating to fusion/pseudofusion and the adjustment of the window as taught by Levine since such modification would provide a pacing system and method with the use of a plurality of windows with a window relating to fusion/pseudofusion in order to terminate pacing and help conserve power and/or extend the life of the power supply and to use an adjustment of one of the windows to account for conduction delays.

Claims 39, 41-43, 48-53, 92, and 93 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schroepel in view of Levine (as discussed above). Schroepel in view of Levine states in column 1 that the system will dynamically/automatically adjust the stimulation energy so that capture is successful and

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therefore will apply the system/method over several pacing cycles using different energy levels until capture is assured.

In the alternative, Schroepfel in view of Levine discloses the claimed invention except for using the system/method over several pacing cycles (a sequence of pacing cycles) using different energy levels. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the capture system and method as taught by Schroepfel in view of Levine, with using the system over several pacing cycles using different energy levels since it was known in the art that capture systems and methods operate over a sequence of several pacing cycles using different energy levels in order to adjust the stimulation energy to safely capture the heart using the lowest possible energy.

Claims 2, 40, 77, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroepfel (Rueter or Vonk) in view of Levine. Schroepfel (Rueter or Vonk) in view of Levine discloses the claimed invention except for the detection of cardiac noise and canceling classification based on the noise. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac system and method as taught by Schroepfel, Rueter, or Vonk, with the detection of cardiac noise and canceling classification based on the noise since it was known in the art that cardiac systems and methods use detection of cardiac noise and cancel the classification based on the noise so that the system does not falsely detect noise as a cardiac signal and incorrectly adjust the system based on the noise data.

Claims 10, 11, 15, 26-35, 37, 45, 52-55, 57, 67, 68, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroepfel (Rueter or Vonk) in view of Levine.

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Schroeppel (Rueter or Vonk) in view of Levine disclose the claimed invention except for the use of capture, evoked, non-capture, intrinsic templates using captured response beats or intrinsic beats as the template and updating the template, and the peak width, peak amplitude, peak time, or curvature for classifying the signal as capture, evoked, non-capture, intrinsic, by comparing it to a reference. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the capture/threshold system and method as taught by Schroeppel (Rueter or Vonk) in view of Levine, with the use of capture, evoked, non-capture, intrinsic templates using captured response beats or intrinsic beats as the template and updating the template, and the peak width, peak amplitude, peak time, or curvature for classifying the signal as capture, evoked, non-capture, intrinsic, by comparing it to a reference since it was known in the art that capture/threshold systems and methods use: the use of capture, evoked, non-capture, intrinsic templates using captured response beats or intrinsic beats as the template and updating the template to provide a system/method that reduces processing to clearly distinguish and accurately match the sensed cardiac signal to a determined condition of the heart, and that periodically updates and creates the templates to match the current state of the patients heart; and the peak width, peak amplitude, peak time, or curvature for classifying the signal as capture, evoked, non-capture, intrinsic, by comparing it to a reference to allow the system/method to use conventional and tested morphological parameters to correctly detect the capture, non-capture, intrinsic, or evoked state of the heart due to the pacing pulse.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. In addition, the prior art previously cited or in the

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information disclosure statements show several examples of many of the well known in the art elements/steps discussed in the 103 rejections.

Allowable Subject Matter

Claims 18, 36, 38, 56, 58, 63, 65, 70, and 88 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-17, 19-35, 37, 39-55, 57, 59-62, 64, 66-69, 71-87, and 89-94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9, 16, and 17 AND claims 4, 5, 7-10, 15, 16, 19-21, and 29-31, AND claims 24-34, 38, 41, 56, and 61 AND claims 1-61 of copending Application No. 11/180937, 11/116565, 10/735519, 10/734599, respectively. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the copending application's claims are narrower and meet the limitations of this application's claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include such items as the defining a classification window based on a timing of a cardiac signal, detecting peak width, noise, slope, amplitude, curvature, the threshold tests, etc in the method and system as taught by this application's claims since such items aid in determining the capture threshold and thereby reduce the amount of energy needed to deliver the pacing pulses.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

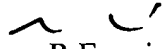
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

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